

Burnside Does Not Teach or Suggest The Claimed Temperature Sensor

The Examiner relies upon the combination of the temperature sensors in Burnside with either of the structures disclosed in Paraschac or Yates to reject independent claim 50. However, it is respectfully submitted that such combinations do not teach or suggest the claimed invention of amended claim 50.

Relative to the combination of the cited references with Burnside, the Examiner relies upon a “temperature sensor (299)” in Burnside, which appears in Figure 68. However, the element 299 is actually disclosed as a “porous material coating” in column 38, lines 42-45 and is not a temperature sensor.

Further, any temperature sensors that are disclosed in Burnside do not teach or suggest “at least one temperature sensor associated with at least one jaw and disposed to sense the temperature of cardiac tissue at a location laterally spaced from the tissue contacting portion of the conductive member such that the temperature sensor can detect undesired thermals spread in the compressed tissue that is located outside the selected ablation area,” as recited in claim 50.

First, only one temperature sensor is actually shown on the disclosed ablation probe in Burnside. Such sensor is described as a reference temperature sensor 324 (in Figure 71a) or thermocouple 511 (in Figure 89). In Figure 71a, the reference temperature sensor 324 is located in the handle 312 of a probe 308 “so that room temperature will be used as the reference.” Column 32, lines 65-67. Although other locations of the reference temperature sensor are described at Column 33, lines 1-14, Burnside clearly teaches that the reference temperature sensor provides a common reference temperature for comparison to a plurality of temperature sensing elements

(not shown in Figure 71a) that respectively sense the temperature of a plurality of electrode elements 294.

In particular, in Figure 89, Burnside expressly describes that “multiple sensing elements comprise thermocouples 508, 509, and 510 [that are] individually associated with the multiple emitters of ablating energy, which comprise electrode regions 501, 502, and 503.” Column 47, lines 34-37. (Emphasis added). As further described in Burnside, the activation of the electrode elements 294 (or electrodes 501, 502, 503) is individually controlled based on the difference between the common reference temperature sensor 324 (or thermocouple 511) and the respective thermocouple 508, 509, 510 that senses the temperature of the respective electrode:

The voltage inputs from the thermocouples 508, 509, 510 and 511 are sent to front end signal conditioning electronics. The inputs are amplified by differential amplifier 526, which reads the voltage differences between the copper wires of the thermocouples 508/509/510 and the reference thermocouple 511. The voltage differences are conditioned by element 527 and converted to digital codes by the analog-to-digital converter 528. The look-up table 529 converts the digital codes to temperature codes. The temperature codes are read by the microcontroller 531.

The microcontroller 531 compares the temperature codes for each thermocouple 508, 509, and 510 to preselected criteria to generate feedback signals... These feedback signals control the interface power switches 514 via the interface 530, turning the electrodes 501, 502, and 503 off and on. (Column 48, line 65 to Column 49, line 14) (Emphasis added).

Thus, in contrast to the claims, such reference temperature sensor controls activation of the multiple electrodes based on comparison of the electrode temperature to a common reference temperature and is not disposed to sense the temperature of cardiac tissue at a location laterally spaced from such electrodes for detecting undesired thermal spread of the treated tissue.

It is presumed in the Office Action that it would have been obvious or routine to laterally space the temperature sensor from the tissue contacting portions of the conductive members in Burnside. However, it is respectfully submitted that Burnside is directed to solving a different problem and teaches away from such modification so that the subject matter of amended claim 50 would not have been obvious, and would certainly not be routine, to a person of ordinary skill in the art.

Burnside is an attempt to address the problem of maintaining a uniform distribution of temperatures among multiple electrode elements 294 and it does this by monitoring the temperature of each electrode element 294 relative to a common reference temperature sensed by the reference temperature sensor 324. As clearly described in Burnside, “the system 500 distributes power to the multiple electrode regions 501, 502, and 503 to establish and maintain a uniform distribution of temperatures along the ablating element. In this way, the system 500 obtains safe and efficacious lesion formation using multiple emitters of ablating energy.” (Column 49, lines 29-34) (Emphasis added). Thus, the location of the reference temperature sensor in Burnside is disposed to provide a common reference temperature relative to the sensed temperature of each electrode so as to provide an uniform electrode temperature across the entire ablation device, in contrast to claim 50.

Further, it would not have been obvious to modify the location of each electrode temperature sensor –to which the reference temperature is compared. Burnside expressly describes the importance of the location of the plurality of temperature sensors (or thermocouples 508, 509 and 510) to be individually associated with a respective electrode to sense the temperature of the electrodes for individual

comparison to the reference temperature. The disclosed location of such temperature sensors in Burnside provides for sensing of the respective electrode temperature at column 32, lines 60-64:

A plurality of temperature sensing elements (such as thermocouples which are not shown) may be located on, under, abutting the longitudinal end edges of, or in between, the electrode elements 294 in any of the exemplary devices disclosed herein. (Emphasis added).

Thus, the plurality of temperature sensor elements in Burnside are each disposed to sense the temperature of electrodes through which RF electrical energy is conducted for comparison to the common reference temperature sensed by the reference temperature sensor 324.

In contrast, the present invention is directed to sensing the temperature of tissue spaced from the ablation zone to monitor for undesirable thermal spread. Thermal spread is not the problem addressed in Burnside and the Burnside structure is not the solution. Indeed, Burnside represents that the electrodes are subjected to less heating due to the high conductivity of the electrodes and fails to even address any thermal spread in the tissue. To the extent Burnside acknowledges the temperature of tissue, it does so only with respect to the effect of the tissue temperature on the sensed temperature at the electrode. – i.e., “heat will be drawn from the tissue to the electrode as RF power is applied to the tissue” (column 52, lines 30-31) and “electrode temperature will eventually approach the tissue temperature.” (column 52, lines 34-35). In any event, Burnside dismisses any difference between the tissue temperature and the sensed temperature at the electrode, as it states “the difference between the plateau tissue temperatures and the sensed temperature [at the electrode] can typically be disregarded.” Column 52, lines 42-44.

So, a fair reading of Burnside is that the structure there does not relate to the problem addressed by the present invention, does not provide the solution claimed in the present invention and teaches away from even a recognition of thermal spread as a potential issue.

In summary, in contrast to Burnside, the claimed invention provides for at least one temperature sensor that allows for sensing tissue temperature at a location that is laterally spaced from the tissue contacting portions of the conductive members such that the temperature sensor can detect undesired thermal spread in the compressed tissue that is located outside the selected ablation area.

For the above reasons, reconsideration and allowance of claim 50 and its respective dependent claims are respectfully requested.

The Cited References Are Not Combinable And Do Not Teach or Suggest The Claimed Apparatus For Other Reasons

Further, it is respectfully submitted that Burnside is not properly combinable with Paraschac or Yates and/or such references do not teach or suggest the claimed invention for other reasons.

First, the cited references to Paraschac and Yates are each directed to apparatuses for coagulation and cutting of tissue, and not for forming limited lines of ablation. Each of their disclosed apparatuses teaches a structure that is distinctly different from the claimed ablation apparatus. The claimed ablation apparatus provides for an electrical current through tissue between the jaws only to the extent necessary to form scar tissue to disrupt or break the pathway of an aberrant electrical impulse of the cardiac tissue without causing undue damage to cardiac tissue that may result from cutting, coagulation, sealing or welding such tissue. This is highly different from

coagulating and cutting of tissue and such technologies, are not merely interchangeable, as the Office Action seems to suggest. Accordingly, it is respectfully submitted that Paraschac and Yates are not properly combinable with the RF ablation apparatus disclosed in Burnside.

Further, each of the cited references teaches or suggests a relative wide treatment zone that effectively spans the width of the jaw's clamping surface. For example, Burnside teaches electrodes 294 that conduct electrical current across a treatment zone that essentially extends along the entire width of the probe or jaws. Both Paraschac and Yates also teach a treatment zone that effectively spans the entire width of the jaws for cauterizing a wide area of tissue prior to cutting to reduce bleeding.

For these added reasons, it is respectfully submitted that the subject matter of amended claim 50 would not have been obvious in view of Burnside either alone or in combination with any of the other cited references.

Dependent Claim 57 Complies With Section 112, First Paragraph

With respect to the Section 112, first paragraph, rejection of dependent claim 57, it is respectfully reiterated, as stated in the prior response, that the relevant case law supports that there is no requirement that all the claimed features must be shown in the same embodiment.

As set forth by the Federal Circuit in JVW Enters. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005), citing Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc), it is improper to "import limitations into claims from examples or embodiments appearing only in a patent's written description", even when a specification describes very specific embodiments of the invention or even describes

only a single embodiment, unless the specification makes clear that ‘the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.’” (emphasis added).

The present application makes clear that it does not intend for the claims and the embodiments to be “coextensive” with a single disclosed embodiment. Relative to claim 57, it is noted that the claimed subject matter -- “at least one of the conductive members defines an interior lumen” – is disclosed in an embodiment that is described and shown at paragraphs 23 and 97 and in Figure 6 of the published application. Although Figure 6 does not also show the temperature sensor of independent claim 50, from which claim 57 depends, the specification makes clear that it does not intend for the claims and embodiments to be strictly coextensive with any particular disclosed embodiment.

For example, the specification shows at Figures 3-6 alternate constructions of ablating elements – one of which shows the conductive member defining an interior lumen -- for the arrangement of jaws shown schematically in Figure 1 – and other alternative jaw arrangements are disclosed, for example, in the embodiments of Figures 32 and 39, which include a temperature sensor. Also, paragraph 200 of the published application expressly sets forth that “[w]hile the invention has been described in terms of certain preferred embodiments, there is no intent to limit the invention to the same.” (Emphasis added). Thus, no one embodiment is intended to be interpreted as strictly coextensive with the claimed subject matter.

Thus, it is respectfully submitted that the claims may include a combination of features from different disclosed embodiments, as clearly contemplated by the specification, and that the rejection of claim 57 under Section 112 should be withdrawn.

Co-pending Application

As a courtesy to the Examiner, applicant respectfully refers to co-pending U.S. Application Serial No. 10/920,574, filed August 18, 2004, which is a divisional of U.S. Patent No. 6,974,454. The '574 application and its parent include claims relating to a temperature sensor or thermocouple.

Conclusion

For all the above reasons, reconsideration and allowance of claims 50-58 are respectfully requested.

Respectfully submitted,

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